GUIDELINES FOR REVIEWERS' WRITTEN COMMENTS

NIDDK MIDCAREER INVESTIGATOR AWARD IN PATIENT-ORIENTED RESEARCH (K24)

The K24 award is intended to provide support for clinicians so they may devote protected time to patient-oriented research and to serve as mentors for beginning clinical investigators. Refer to the NIH Guide announcements (PA-00-005, 10/8/99) for more detail about the award. The format outlined below should be followed in preparing your comments for each K24 application assigned to you. Include additional headings when they seem appropriate to the review. If this is a competing renewal application, evaluate the progress made during the previous funding period. If this is an amended application, address progress, changes, and responses to the critique from the previous review, indicating whether the application is improved, the same as, or worse than the previous submission. However, you are not constrained to address only the points identified in the previous review. These comments on progress and/or responsiveness to previous critiques may be provided either in a separate paragraph and/or under the appropriate criteria.

Resume: In a brief paragraph, indicate the major strengths and weaknesses of the proposed program as a means of allowing the investigator to conduct patient-oriented research and to serve as a mentor, and how these factors determine your overall merit rating of the application.

Description: (optional) Briefly describe the research outlined, or use the abstract from the application.

Investigator: Describe and evaluate the investigator's record of independent, patient-oriented research, including publications and relevant active or recent (last five years) grant support; qualifications to serve as a mentor; and commitment (25-50 percent time) to patient-oriented research. Consider how this award will allow the investigator to contribute and devote time to his/her research program and mentoring. In general, the investigator should be within 15 years of his/her specialty training.

Research Plan: Assess the research plan outlined, including the specific aims, background and significance, progress report/preliminary studies, and research design and methods for its feasibility, scientific soundness, and potential to achieve the goal of this award. If plans for inclusion and protection of human subjects are inadequate, this should be considered a research design flaw. Evaluate the adequacy of the investigator's proposed commitment and resources to achieve the goals of the award.

Mentoring Plan: Evaluate the investigator's record of mentoring or training clinical investigators and the plans to provide mentoring opportunities to beginning clinical investigators under the auspices of this award.

Environment And Institutional Commitment: Evaluate the institution's patient-oriented research and training program relative to the investigator's area of expertise. Assess its commitment to the investigator through allowing him/her protected time and resources to pursue the training and research.

Action: The application may be recommended for no further consideration, deferred in order to obtain additional information, or given a priority score. If the application is to be scored, indicate the level of scientific merit using the adjectival scale.

Budget: Comment on the appropriateness and justification of the budget request within the context of the goal of the award. The investigator's maximum salary may not exceed the NIH salary cap, commensurate with effort. Up to $25,000 per year is allowed for research expenses such as supplies, equipment, and technical personnel; travel to research meetings or training; and statistical services including personnel and computer time. Any equipment requests must be justified adequately. Justify any proposed changes.

Other Considerations: If these matters affect the assessment of the scientific merit of the application, they will be considered as part of the critique and the overall score.

Involvement of Human Subjects: Explain concerns regarding the proposed use of human subjects, including any possible physical, psychological, or social injury individuals might experience while

participating as subjects in the research. Indicate whether their rights and welfare will be protected adequately or whether they may be subjected to ethically questionable procedures. Determine if an appropriate balance of gender and minority representation in the study population will be sought, if this is scientifically acceptable, and justify the gender and minority codes to be assigned. For applications submitted after October 1, 1998, determine whether children have been included in the research and if their inclusion or exclusion has been explained adequately to justify the code to be assigned. If a data and safety monitoring plan is required, indicate if it is adequate. For additional information, refer to the "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications."

Animal Welfare: If animals are to be used in the project, discuss if their use is justified and if they will be given proper care and humane treatment so that they will not suffer unnecessary discomfort, pain, or injury.

Hazardous Materials and Procedures: Describe any potentially hazardous materials and procedures and whether the protection to be provided will be adequate.